

## **Participant Informed Consent Form**

**Study Title:** Internet-based cognitive behavioral therapy for tinnitus in the United States: A randomized controlled trial protocol

**Clinical trial registration:** NCT04004260 on 2 July 2019.

**Funding:** National Institute on Deafness and Communication Disorders (NIDCD) of the National Institute of Health (NIH) under the award number R21DC017214.

**Ethical approval:** Institutional Review Board at Lamar University, Beaumont, Texas, US (IRB-FY17-209).

**Document Date:** June 22, 2021

**Title of Project**

Cognitive Behavior Therapy delivered via the Internet for adults experiencing tinnitus

**Principle Investigator**

Dr. Vinaya Manchaiah, Jo Mayo Endowed Professor, Lamar University, USA

**Co-Investigators**

Dr. Eldre Beukes, Post-doctoral Researcher, Lamar University, USA

Ms. Marifer Munoz, Graduate Research Assistant, Lamar University, USA

**Study Information & Procedures**

Dear Sir/Madam

Experiencing tinnitus may be very distressing, due to hearing unwanted sounds, such as ringing or buzzing. Many aspects of daily life, such as sleep, mood and concentration may be affected as a result of having tinnitus. Ensuring readily accessible specialist tinnitus clinical services throughout the country is desirable, but difficult to implement, due to the burdens on the current health care system. Innovative ways of helping those with tinnitus, as well as manage the related health care burden, is required. There are several approaches to tinnitus management but the one with the best evidence - cognitive behavioral therapy (CBT) - is rarely offered (less than 1% in the US), and there is a lack of trained audiologists who can deliver this treatment. One partial solution is to offer CBT via the Internet as a guided self-help program. Evidence from studies in Europe clearly suggests that this is as effective as seeing a clinician with medium to large effects. However, not all patients are suitable and it is important to assess medical aspects before starting online CBT. This project involves adapting and testing the effectiveness of an Internet-based cognitive behavioral therapy (iCBT) for tinnitus sufferers in the USA.

If you are experiencing tinnitus and looking for management options you can consider participating this study. This self-help program is for 8 weeks and can be done at your own time and at home. However, you need internet access and a few hours of time commitment each week.

Participation in this study is voluntary and deciding not to participate will not affect you in anyway. If you decide to participate, we request you to kindly complete a questionnaire. All the information recorded will be kept confidential and stored in an encrypted manner.

We are happy to answer any questions you may have before the start of this study.

Dr. Vinaya Manchaiah

*Jo Mayo Endowed Professor*

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**Time requirements**

This is a treatment study and requires you to participate for 8 weeks. We anticipate that you need to spend about 2 hours a week reading self-help materials, completing exercises and also record your progress. In addition, we will also follow up your progress 12 months following the study by means of a questionnaire that will be emailed to you.

**Sponsorship and Disclosures**

This work is funded by the National Institute on Deafness and Communication Disorders (NIDCD) of the National Institute of Health (NIH) under the award number R21DC017214. The investigator does not have any conflict of interest.

**Risks and/or Discomforts**

The risks and or discomforts associated with this study are minimal. You will be asked read some materials about tinnitus and compare them to your own. You will have the opportunity to communicate with the researcher online using secured messaging system anonymously. If you for any reason develop depression or anxiety as a result of reading the self-help materials or answering questions you will be directed to consult other health professionals at your own time and cost. You can also consult a Clinical Psychologist at Lamar University. However, participants can withdraw from the study anytime without penalty.

**Confidentiality**

All records of participants in this study will be kept confidential. All the information is stored in secured computers at Lamar University and the data will be encrypted. In addition, your personal information will be used only by study investigators to contact you about the study. We will only download anonymized data without any personal information for further analysis.

**Benefits**

You may or may not benefit from participating in this study. However, we anticipate you may have some help as these materials have been tested with tinnitus patients in Europe and found to be useful.

**Costs/Financial Considerations**

There are no costs at all to you for participation in this study.

**Reimbursement/Payment**

You will not receive payment for participation in this study.

**Questions**

If you have any questions during or following your participation in this research, please contact Dr. Vinaya Manchaiah at (409) 880 8920 / [vinaya.manchaiah@lamar.edu](mailto:vinaya.manchaiah@lamar.edu). If you have any questions about your rights as a research participant you may call the Institutional Review Board (IRB), Dr. Srinivas Palanki, Associate Provost for ORSPA at (409) 880 7848.

**Voluntary Nature of Participation**

Your participation in this study is voluntary. Please complete the following details electronically to provide your consent to participate in this study.

	<b>Click Here to Consent</b>
I understand that participating in this study is totally voluntary.	
I understand that all my personal information and individual results will be kept confidential.	
I understand that information about the trial will be posted in ClinicalTrials.gov website	
I understand this is a self-help intervention that lasts for 8 weeks. I agree to do my best to work on the suggestions made to help me better manage my tinnitus for about 2 hours each week.	
I agree to complete a questionnaire 1 year following completing the intervention to evaluate my progress at that stage.	

By signing (TYPE YOUR NAME) below, you agree to participate in the project.

**Name:** \_\_\_\_\_ **Date:** Recorded automatically

You can [print/download](#) a copy of this Consent Form to keep and refer to at any time.